

FIG. 1

FIG. 2 is a block diagram of a system architecture for a biomedical data warehouse. The system includes a web portal (108) that interfaces with multiple entities (100) including a first entity, a second entity, and an Nth entity. The web portal (108) is connected to a collection of GUIs (104) including a discovery data collection GUI, a clinical studies data collection GUI, an FDA approval GUI, and a product release data collection GUI. These GUIs are connected to a biomedical data warehouse (44) which stores various metadata structures (106) including a discovery metadata data structure, a clinical studies metadata data structure, an FDA approval metadata data structure, and a product release metadata data structure.

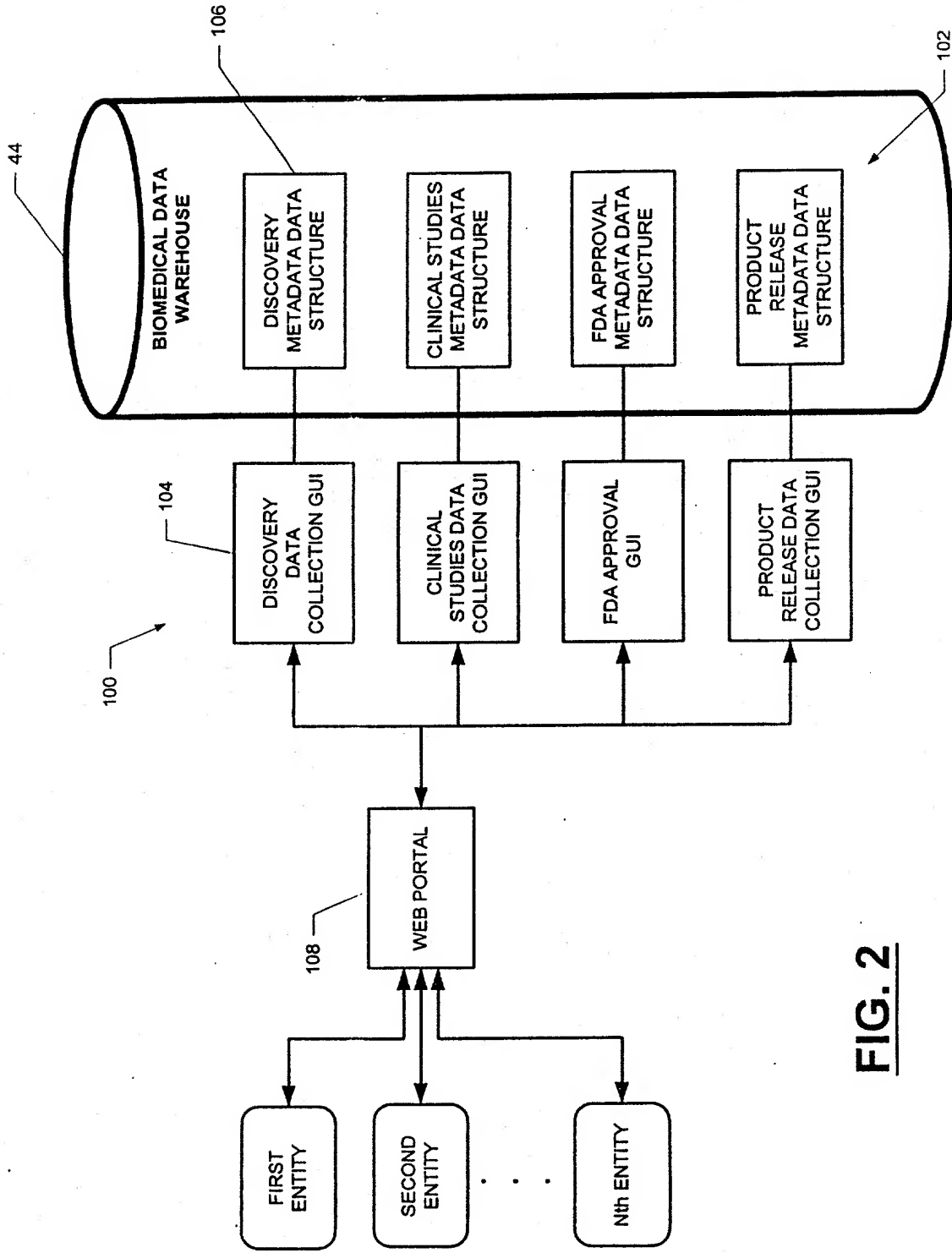


FIG. 2

Administration route:	Intravenous drip	Other:	
Formulation:	aqueous		
Date Explorer enabled?:	<input checked="" type="checkbox"/>		150
Patient column:	studyid.subjid		152
Visit column:	Visit		154
Study period column:			
Number of periods:	3		
Baseline value of visit:	0		
Titles and Footnotes:	Edit		

FIG. 3

Columns		Name	Label	Display options	Type	Length	Journal	Index	add	edit	delete	add key
<input type="checkbox"/>	age		Age in Years at Baseline		Numeric	8	BES112	F12				
<input type="checkbox"/>	studyid		Actual Day of Visit/Collection/Exam		Numeric	8	BES112	F12				
<input type="checkbox"/>	HEIGHT		HEIGHT in Centimeters		Numeric	8	BES112	F12				
<input type="checkbox"/>	Invest		Investigator Name		Character	4	%4	%4				
<input type="checkbox"/>	race		Race		Character	8	%8	%8				
<input type="checkbox"/>	sex		Sex		Character	8	%8	%8				
<input type="checkbox"/>	studyid		Study ID		Character	8	%8	%8				
<input type="checkbox"/>	subjectid		Subject ID		Numeric	8	BES112	F12				
<input type="checkbox"/>	trialid		Trial Treatment Code		Numeric	8	BES112	F12				
<input type="checkbox"/>	TRTGrp		Treatment Group		Character	8	%8	%8				
<input type="checkbox"/>	WEIGHT		Weight in Kilograms		Numeric	8	BES112	F12				

[NONE] [NONE] [NONE]

Keys		[2]		[edit] [delete]	
Key name	Description	Key number	Key sort order		
<input type="checkbox"/> studyid	Study ID	1	Ascending		
<input type="checkbox"/> subject	Subject ID	2	Ascending		

FIG. 4

190
 192

Last uploaded from path: G:\VMDAT\Nicaah2\shonk\adverse.aad7\dat

Column	Name	Label/Description	Type	Length	Format	Inform
<input type="checkbox"/>	ecom	Comment	Numeric	8	BEST12	F12
<input type="checkbox"/>	ecodecd	AE Decode from Dictionary	Character	21	\$F21	\$F21
<input type="checkbox"/>	ecodul	Outcome of Event	Numeric	8	BEST12	F12
<input type="checkbox"/>	ecodv	Severity/Intensity of Event	Numeric	8	BEST12	F12
<input type="checkbox"/>	studyid	Study ID	Character	8	\$F8	\$F8
<input type="checkbox"/>	subjid	Subject ID	Numeric	8	BEST12	F12

Default measure definition column:
 Default measure definition column type:
 Default measure grouping column:

Keys	Key Name	Description	Key order	Key sort order
<input type="checkbox"/>	studyid	Study ID	1	Ascending
<input type="checkbox"/>	subjid	Subject ID	2	Ascending

Unique by keys?: ☐

FIG. 5

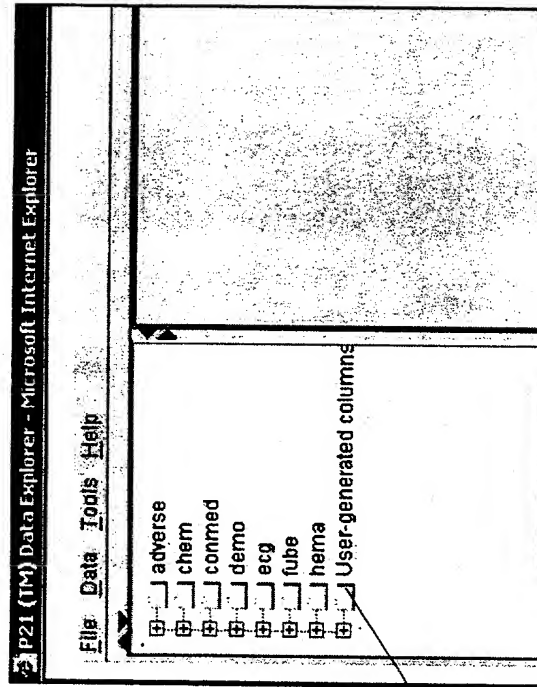


FIG. 6

Source: C:\Program Files\Internet Explorer\Internet Explorer.exe
Address: http://www.microsoft.com/...
Title: Microsoft Internet Explorer

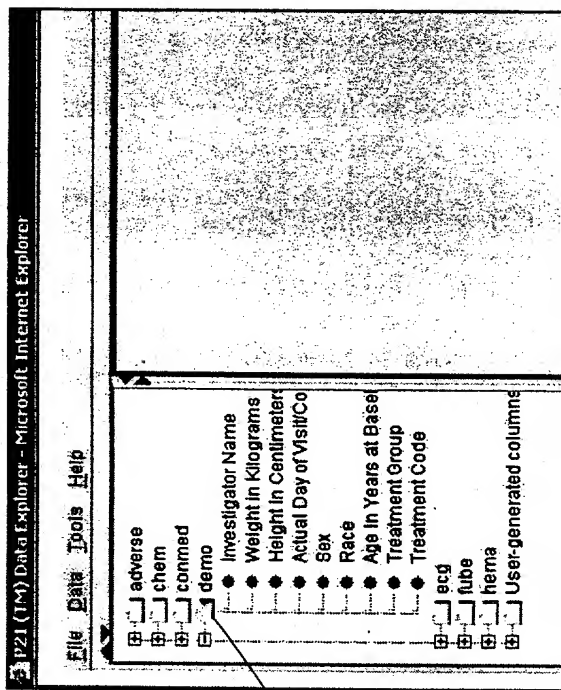
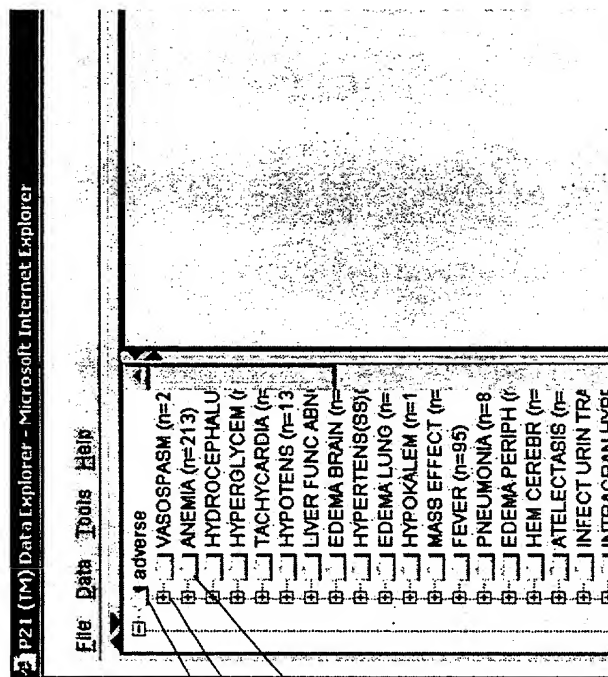


FIG. 7



220

222

224

200

FIG. 8

FIG. 9 is a screenshot of a Microsoft Internet Explorer window displaying a data table. The window title is "p21 (TM) Data Explorer - Microsoft Internet Explorer". The table has columns for PatientID, Sex, Race, and Investigator. The data is organized into rows, with some rows having a "User-generated column" at the end. The table is labeled with reference numerals 200, 230, 232, 234, 236, 238, and 240.

200

232

234

230

238

240

236

PatientID	Sex	Race	Investigat...
1	Male	Caucasian	011A
2	Male	Black	011A
3	Female	Caucasian	011A
4	Male	Other	011A
5	Female	Caucasian	011A
6	Female	Caucasian	011A
7	Female	Caucasian	011A
8	Male	Caucasian	011A
9	Male	Caucasian	011A
10	Male	Caucasian	011A
11	Female	Caucasian	011A
12	Female	Caucasian	011A
13	Male	Caucasian	011A
14	Female	Black	011A
15	Male	Caucasian	011A
16	Male	Caucasian	011A
17	Female	Black	011A

FIG. 9

Report

Basic Summary	prev / next cancel
----------------------	-----------------------

Population Data Set: Name:N:\ar\clinical\CSAH Study D [v]

Grouping Variable: Treatment Code {tctcd}

Variable:	Treatment Code {tctcd}
Race {race}	Age in Years at Baseline {age}
Sex {sex}	Actual Day of Visit/Collection{Exam {dmactdy}}
	Height in Centimeters {HEIGHT}
	Investigator Name {invname}
	Race {race}
	Sex {sex}
	Subject ID {studyid}
	Subject ID {subjld}
	{tctcd} -> Race {race}
	Treatment Group {TRTGAP}
	Weight in Kilograms {WEIGHT}

Summary Statistics:

n	Mean
s	Min
c	Max
d	StdErr
e	Median
f	StdDev

Report (F) Basic Summary
Population Data Set: Patient/Nicardipine/IL-3211 Study 01
Grouping Variable: Treatment Code [trcat]
Analysis Type: DISCRETE
Summary Statistics: N, Mean, Min, Max, StdErr, Median, StdDev

Report (F) Basic Summary prev next cancel

Population Data Set: Patient/Nicardipine/IL-3211 Study 01 Select... Clear

Grouping Variable: Treatment Code [trcat] (see Treatment)

Variable	Analysis Type	Summary Statistics
Race [race]	DISCRETE	N, Mean, Min, Max, StdErr, Median, StdDev
Sex [sex]	DISCRETE	N, Mean, Min, Max, StdErr, Median, StdDev
Age in Years at Baseline [age]		
Actual Day of Visit/Collection/Exam (dmccdyr)		
Height in Centimeters [HEIGHT]		
Investigator Name [invname]		
Race [race]		
Sex [sex]		
Study ID [studyid]		
Subject ID [subjid]		
Treatment Code [trcat]		
Treatment Group [TRTGRP]		

270

FIG. 12

Summary Variables	Treatment Code		
	1 (N=181)	2 (N=184)	Total (N=365)
Race			
Black	41 (22.7)	36 (19.6)	77 (21.1)
Caucasian	130 (71.3)	138 (75.0)	268 (73.4)
Oriental	2 (1.1)	4 (2.2)	6 (1.6)
Other	8 (4.4)	6 (3.3)	14 (3.8)
Sex			
Female	134 (74.0)	112 (60.9)	246 (67.4)
Male	47 (26.0)	72 (39.1)	119 (32.6)
Weight in Kilograms			
n	181	184	365
Mean	69.4	73.4	71.5
Median	67.0	70.0	69.0
Std. Dev	15.80	16.71	16.37
Std. Error	1.17	1.23	0.86
Minimum	38	42	38
Maximum	149	134	149

FIG. 13

FIG. 14 is a block diagram of a data structure for clinical studies. The diagram shows a central box labeled "INTERRELATIONSHIPS" (300) connected to four boxes: "DISCOVERY METADATA DATA STRUCTURE" (302), "CLINICAL STUDIES METADATA DATA STRUCTURE" (304), "FDA APPROVAL METADATA DATA STRUCTURE" (306), and "PRODUCT RELEASE METADATA DATA STRUCTURE" (308). Each of these boxes is further connected to three ovals: "DATASET LEVEL", "MEASURE DEF. & GROUPING LEVEL", and "PROTOCOL LEVEL".

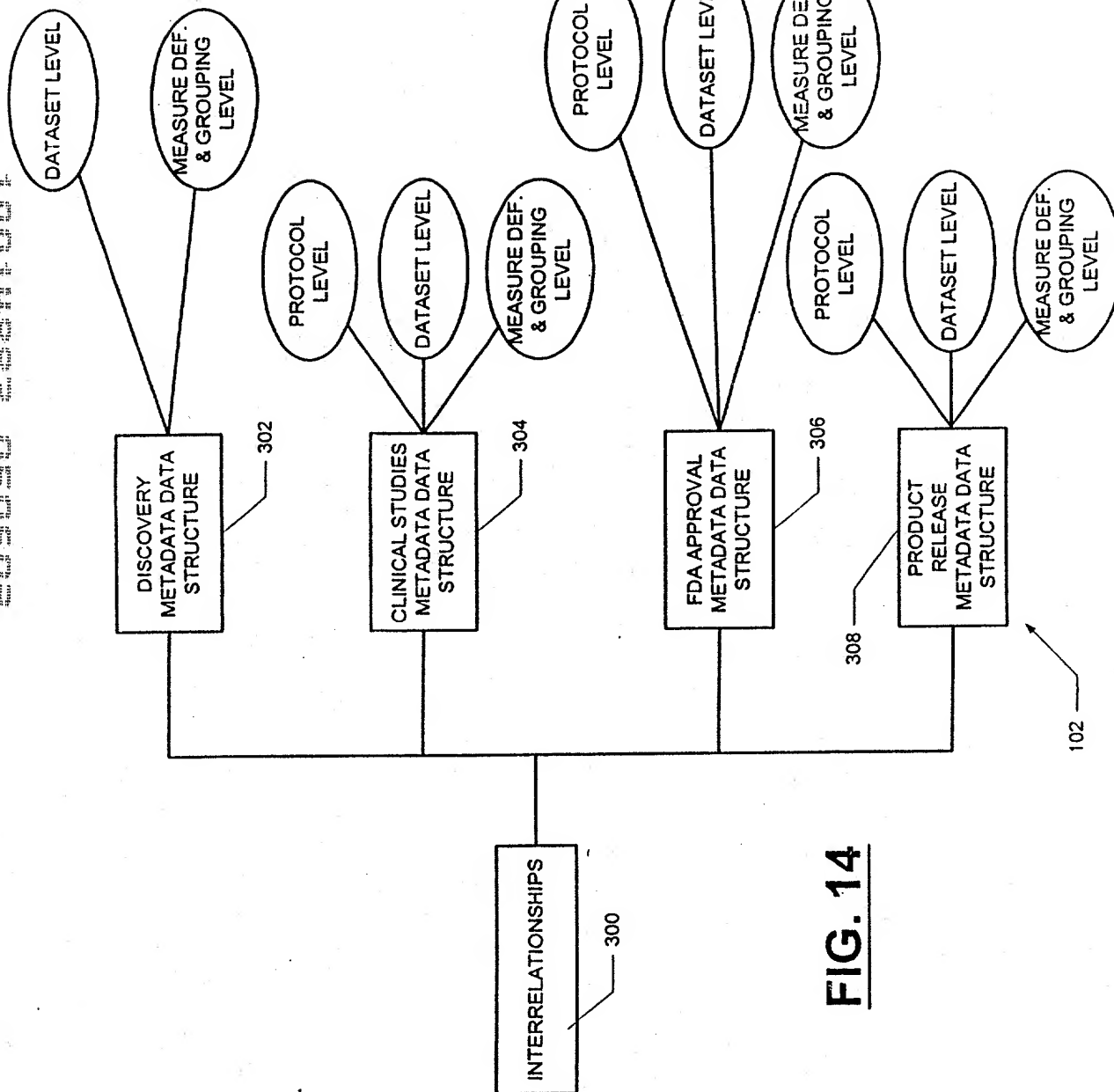


FIG. 14

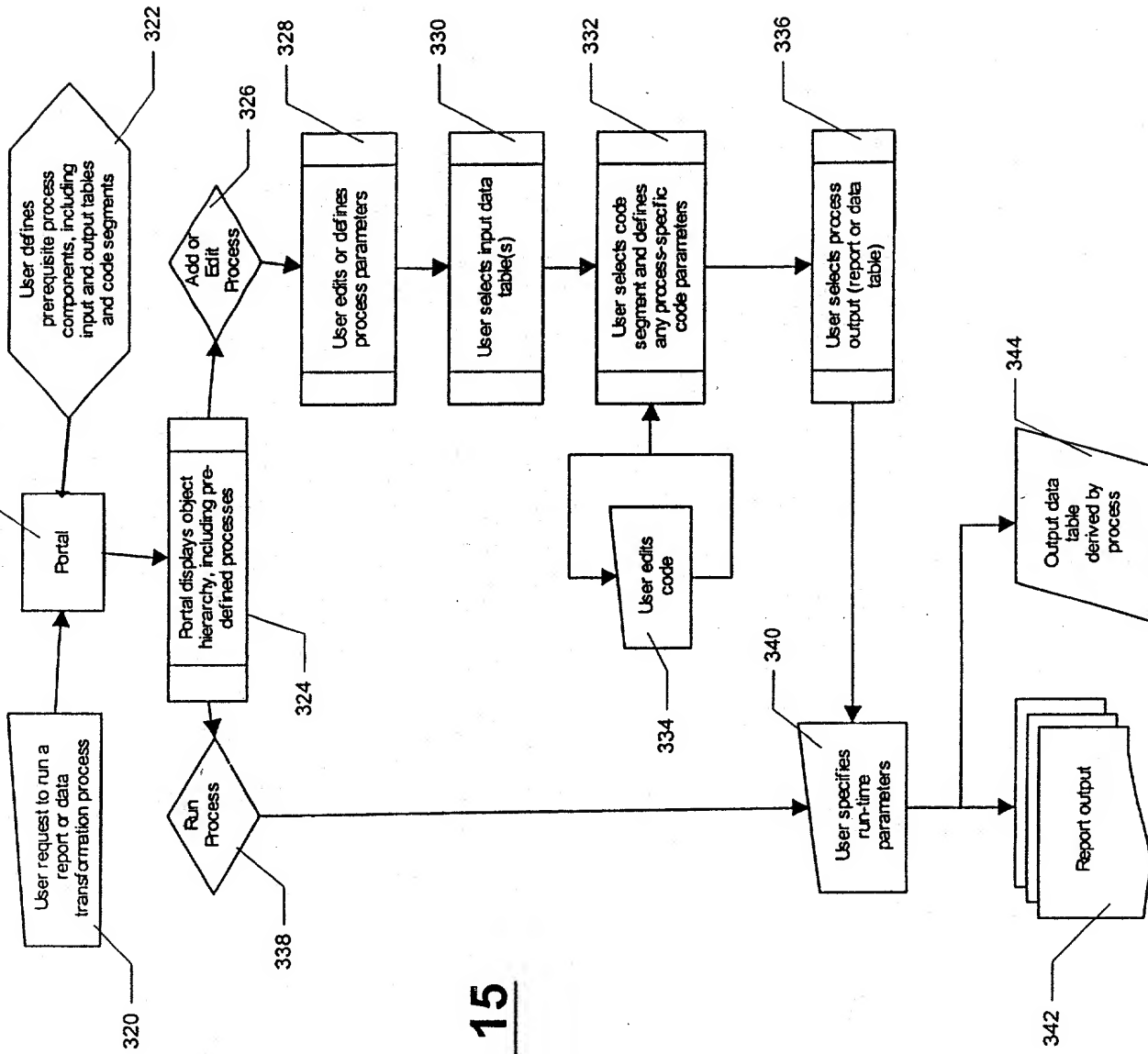


FIG. 15

FIG. 16 is a block diagram of a system architecture for a biomedical data warehouse. The system includes a first entity (400) and a second entity (402). The first entity (400) is connected to a first URL (404) via a solid arrow. The second entity (402) is connected to a second URL (408) via a solid arrow. Both the first URL (404) and the second URL (408) are connected to a web portal (108) via dashed arrows. The web portal (108) is connected to a biomedical data warehouse (44) via a solid arrow. The biomedical data warehouse (44) contains a first biomedical project (406) and a second biomedical project (410).

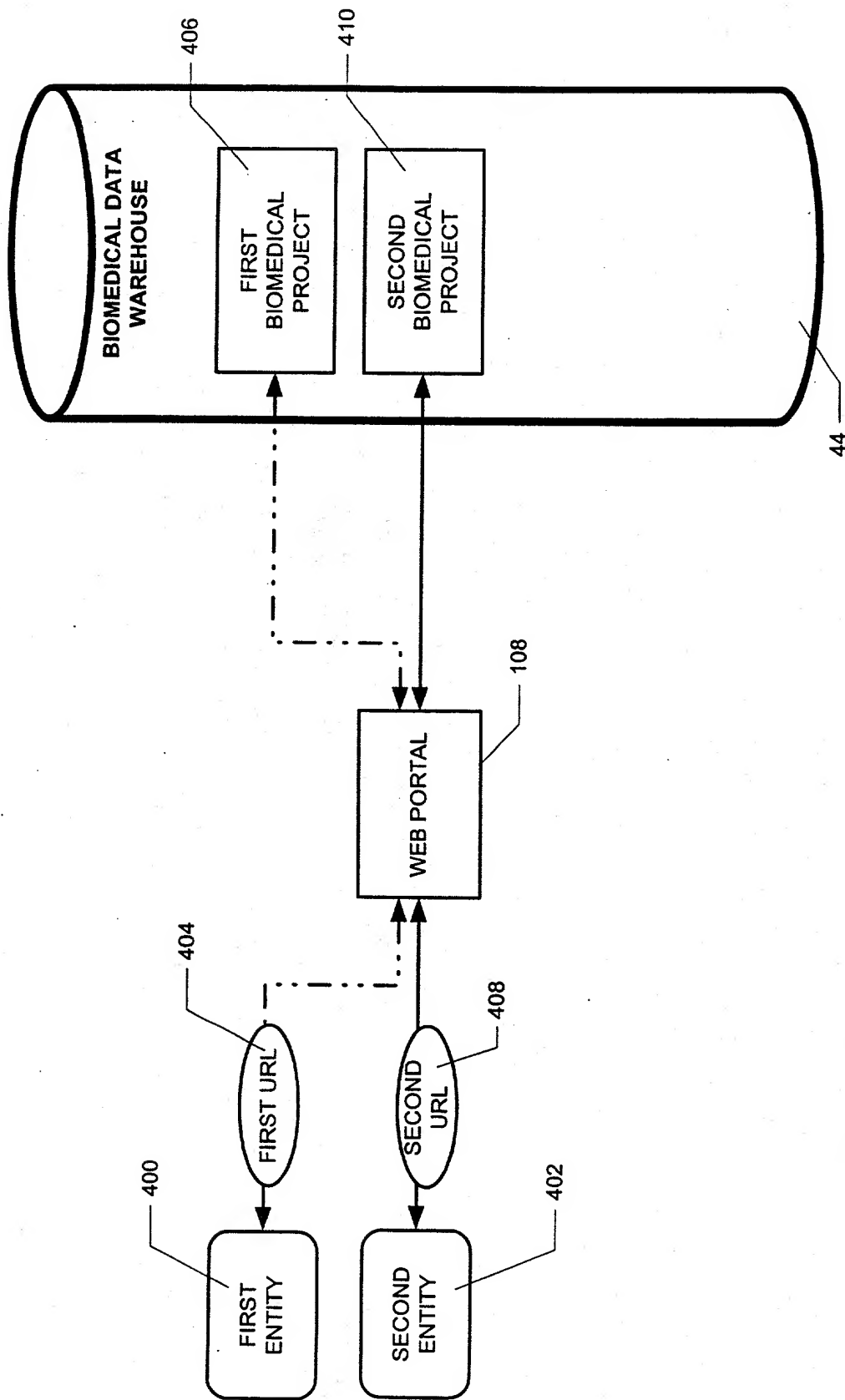


FIG. 16

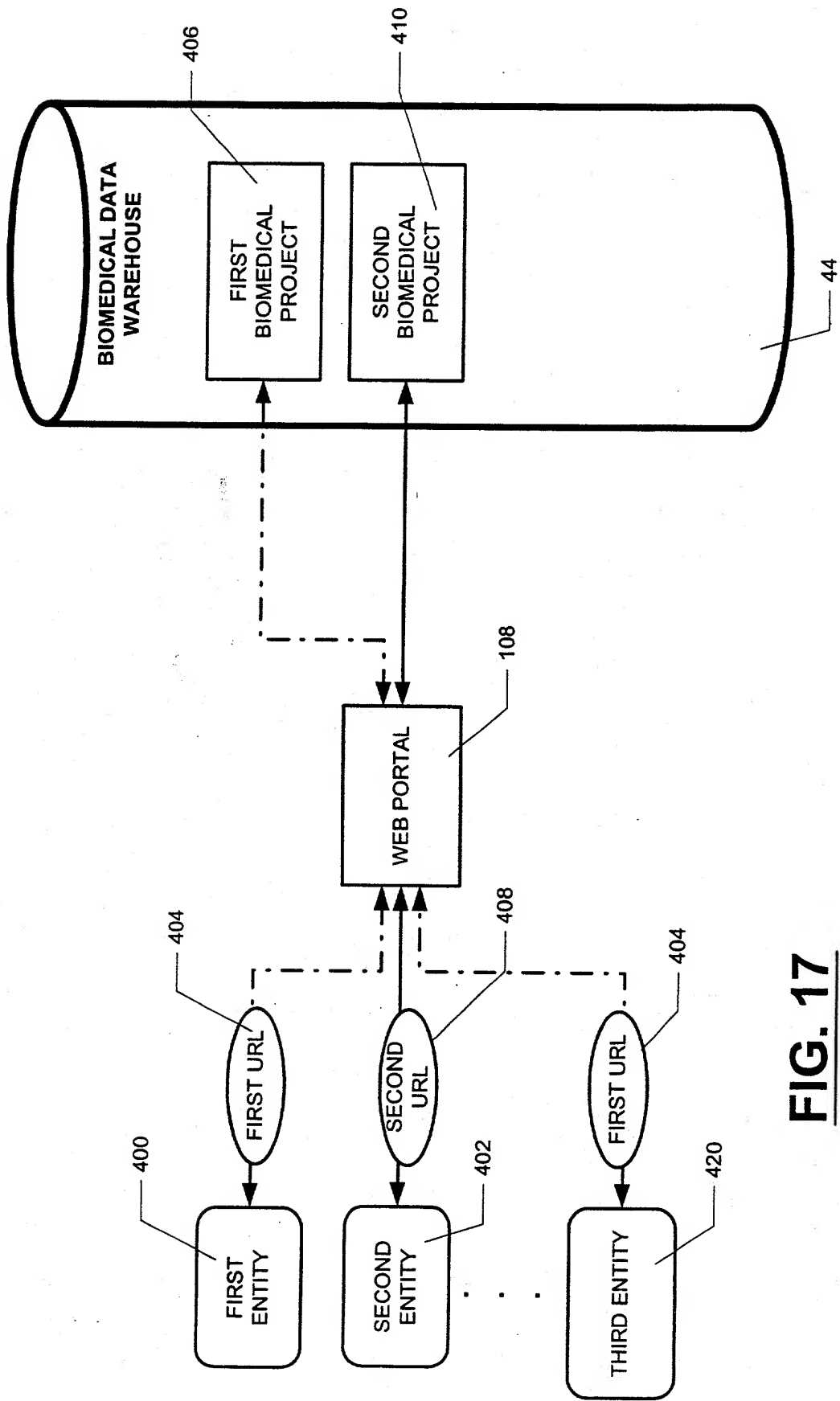
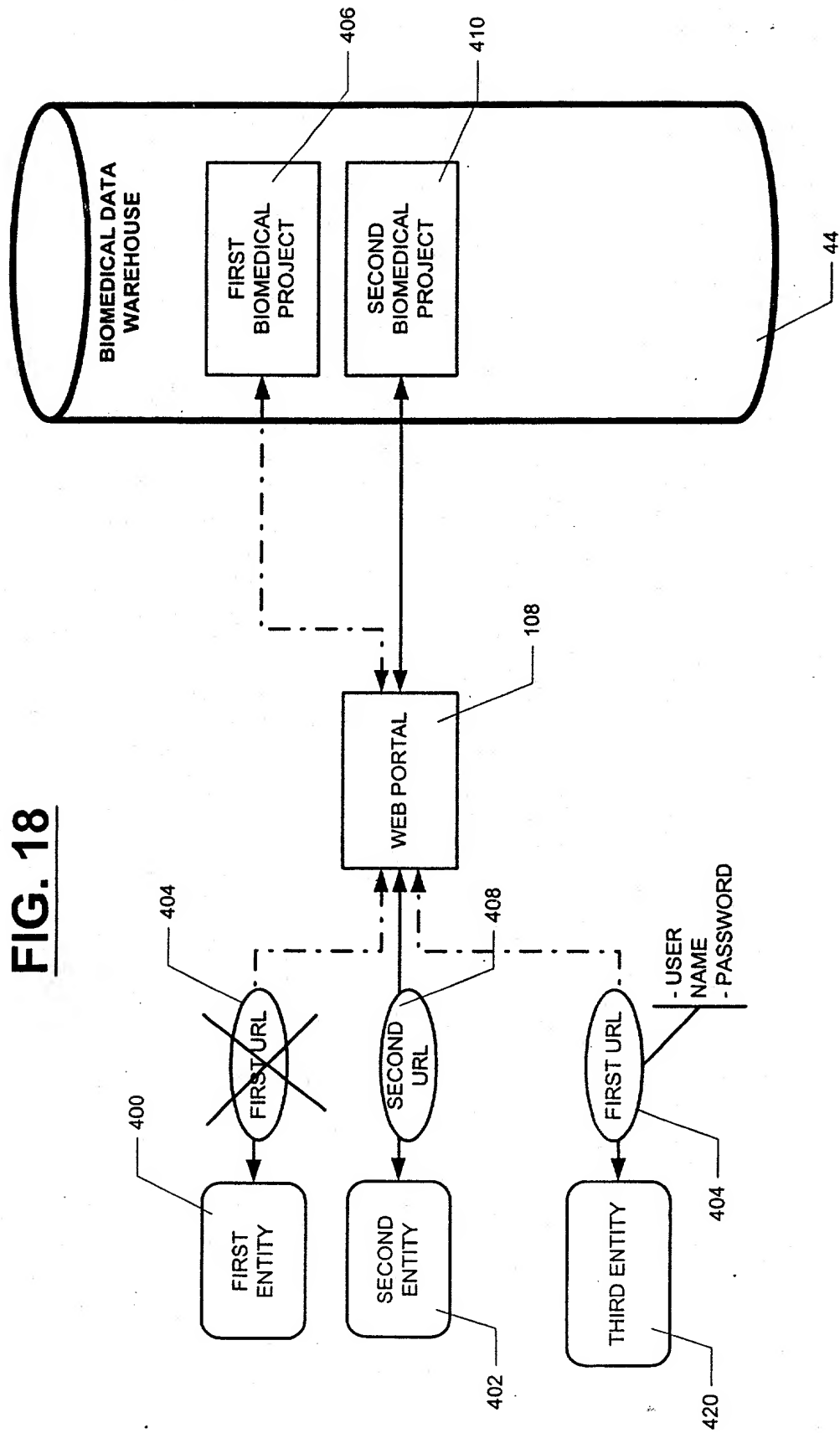
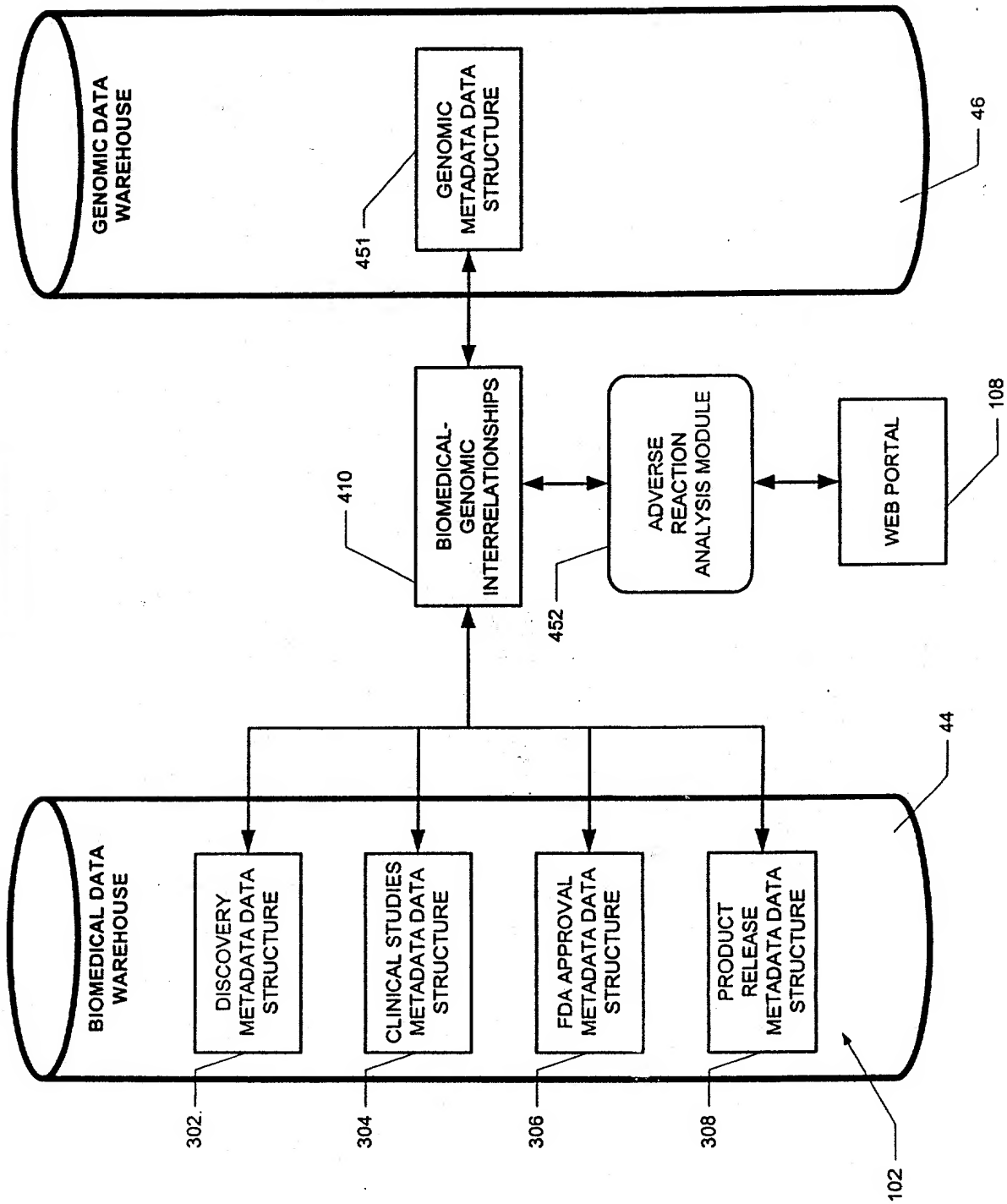


FIG. 17

FIG. 18





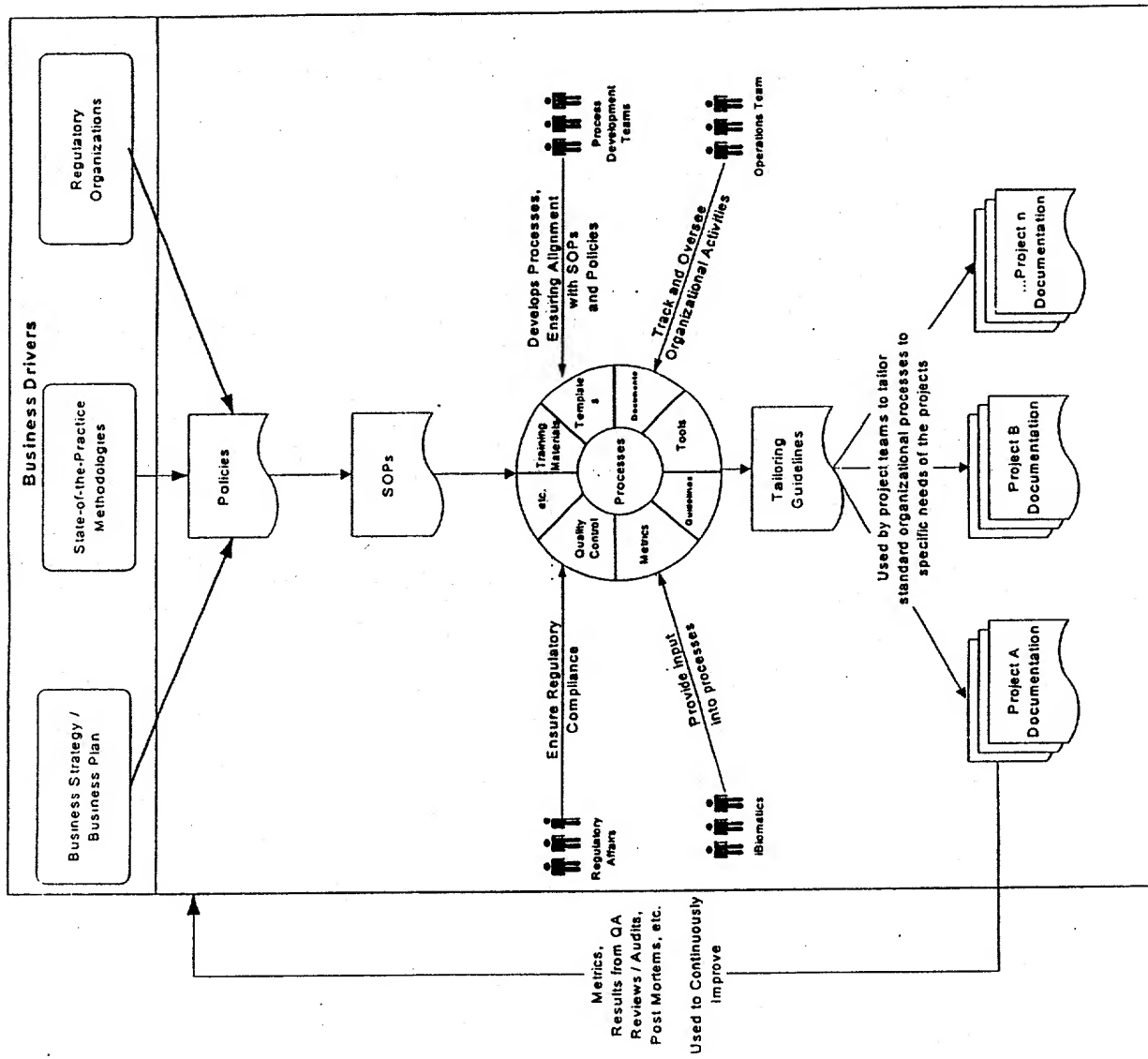


FIG. 20